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Consent Policy Design Group Recommendations

Initial Draft
June 11, 2019

1. Introduction

1.1. Consent Policy Design Group Purpose

The Consent Policy Design Group (CPDG) has been tasked with making recommendations to the Connecticut Health Information Technology Advisory Council that will inform the establishment of patient consent and disclosure policies for the planned health information exchange (HIE) entity that will serve patients and providers in the State of Connecticut. The policy recommendations below are structured as draft policies for consideration by the HIE Entity. This document also includes structure and process recommendations for the ongoing development, refinement and management of the consent policies governing the activities of the HIE Entity.

According to [Sec. 17b-59e or Connecticut Statute](#), within one year of operations of the HIE Entity for hospitals and labs and within two years for health care providers with electronic health records, providers are required to “apply to begin the process of connecting to, and participating in, the State-wide Health Information Exchange.” These policy recommendations support this requirement by the State by providing context for how providers will communicate with patients about their involvement in the HIE Entity.

1.2. Policy Blocks

The consent policies below are presented as “policy blocks.” Each consent policy block can be applied to or more use cases – both those that have been proposed for early Wave 1 development through the Use Case Factory methodology and those that will be developed in the future. For example, the Disclosure Notification policy would apply to all use cases, while an Opt-In policy might apply to a research use case.

For each policy block, the structure of the recommendation includes the following:

- Policy Name
- Purpose
- Application
- Responsibilities of the HIE Entity
- Responsibilities of the Participating Organization
- Responsibilities of the Patient



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Though these are policy recommendations and not final policies, the policy recommendations are presented as declarative statements. The reader should understand that each statement is preceded by an implied "The Consent Policy Design Group recommends that..."

1.3. Use Cases

The Consent Policy Design Group focused its initial work on a single, foundational use case: Patient and Provider Identity and Care Mapping. This use case is fundamental to all activities of the HIE Entity and will be the core capability initially developed. To support this use case, the Consent Policy Design Group is recommending the following draft policy block(s):

- Disclosure Notification Policy
- *Need to determine if there will be other policies related to Patient and Provider Identity and Care Mapping*

The recommended Disclosure Notification Policy was created in anticipation that it will apply to all current and future use cases though, as more complex use cases are developed and the capabilities of the HIE Entity advance, the Disclosure Notification Policy will likely require modifications to accommodate a broader set of circumstances and needs.

1.4. Working Assumptions

To manage the scope of the recommendations produced by the CPDG, the work of developing these recommendations was predicated on several assumptions:

- **Security will be managed appropriately by the HIE Entity. Data is accessible only to those who have a reason to access and their use is monitored and audited.** The group assumes that the HIE Entity will develop the needed security policies and procedures to manage user access; data security in motion and at rest; HIE vendor management; user and vendor auditing; application of breach notification policies; and other security measures that are needed to protect the data entrusted to the HIE Entity as well as those served by the HIE Entity.
- **The HIE Entity will create detailed implementation methodologies and workflow processes to support the final consent policies.** The recommendations of the CPDG provide a high-level framework that can be applied to the creation of operational policies that take into account the technical capabilities and resource constraints of the HIE Entity.
- **Use Cases have been prioritized through the Use Case Factory process. The work of the CPDG is the beginning of an ongoing process for addressing consent policy issues.** Consent is a complex issue and could not have been adequately addressed for all potential use cases through the eight one-hour meetings scheduled for this initial work. The CPDG focused its efforts on a single use case and the policies needed to support that use case with an understanding that additional policies will need to be developed to support other, more advanced use cases.



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2. Recommended Consent Policies

2.1. Disclosure Notification Policy

2.1.1. Name

Disclosure Notification Policy

2.1.2. Purpose

To inform patients and their representatives of the existence of the HIE Entity and notify them of the Participating Organization’s involvement with the HIE.

To give the patient basic information on the nature and purpose of health information exchange and how to seek out additional information on the consent process for participation in the HIE – either through active or passive consent mechanisms.

2.1.3. Application

Applies to all approved HIE Use Cases (currently, Patient and Provider Identity and Care Maps).

2.1.4. Responsibilities of the HIE Entity

- **The HIE Entity will provide content and materials to all HIE participants to support their required patient disclosure notification activities.** The capabilities of participating organizations will vary widely – from multi-facility health systems to large multi-specialty practices to small solo physician practices. The HIE Entity will create and maintain content and materials in multiple forms to accommodate the various types of participating organizations and at a reading level suitable for a general patient population. Particular support should be given to smaller healthcare organizations with few resources to manage these notifications. These materials will include:
 - Sample language for inclusion in the participating organization’s [Notice of Privacy Practices](#).
 - Templates for supplements to Notice of Privacy Practices that can include the participating organization’s name and other identifying information such as location and logo.

The HIE Entity should also consider how they will support non-English language speakers and should look at mechanisms for accommodating patients and their representatives for whom English is not a primary language.

- **The HIE Entity will maintain a website and a customer service capability to address patient and caregiver questions about the details of the services offered and the rights and responsibilities of patients.** The website should be regularly updated with changes to policies and services and should be sufficiently detailed and transparent to give patients and their advocates a full understanding of the role of the HIE Entity; the services it provides; the

Deleted: <#>Non-English language support and translation services as needed to accommodate patients and their representatives for whom English is not a primary language. ¶

governance and legal duties of the organization; links to relevant laws and regulations that apply to the HIE Entity; and the actions a patient can take related to the exchange of their information (e.g., requesting an accounting of HIE activities for their information, opting in or out of certain services, submitting requests for correction of inaccurate information, whom to contact for additional information, etc.). Examples or templates of the legal agreements signed by participating organizations should be made available as well as links to approved use cases and other non-sensitive policy documents governing the HIE Entity.

- **The HIE Entity will publish a continuously updated list of all Participating Organizations and the Use Cases in which they are participating.** This list should include the types of data that are provided by participating organizations and the dates on which these data were made available through the HIE Entity.
- **The HIE Entity will create and maintain a method for patients to sign up to receive regular updates on HIE policies, use cases, and participants.** Patients should be able to learn when their providers expand or change their relationship with the HIE. This could be through an annual or quarterly report directed at consumers or through a customized report specifically for registered and identity-validated patients. The HIE Entity should provide patients with access to reports on overall activity and evolution of exchange in the State of Connecticut and its relationship with regional and national networks.

2.1.5. Responsibilities of the Participating Organization

2.1.5.1. Responsibilities of the Participating Organization – Questions for Discussion:

- Participating Organizations will display information about their participation in the HIE Entity in patient-accessible locations. Information display can include displaying HIE Entity-provided posters and fliers in patient waiting areas, including information about participation in the HIE Entity on the Participating Organization’s website, etc.
- Should Participating Organizations be required to update their Notice of Privacy Practices (NPPs) and make this available to all incoming patients? Should Participating Organizations be required to distribute updates to NPPs to all active patients on a recurring basis (e.g., annually)? Should Participating Organizations be prohibited from submitting patient information to the HIE until that patient has received notification of their participation in the HIE? Should Participating Organizations be required to provide the patient with an updated account of the Use Cases in which they are participating?
 - Proposed language: **Participating Organizations will include information about their participation in the HIE Entity as part of their Notice of Privacy Practices and seek acknowledgement of receipt of this information in compliance with HIPAA regulations.** The information provided should include details about which use cases the Participating Organization is sending or receiving data from the HIE Entity. Participating Organizations should update their Notice of Privacy Practices in a timely fashion whenever they sign on to new use cases. Participating Organizations should make clear to patients whether failure to acknowledge the notification of disclosures to the HIE

Deleted: To be discussed at Meeting 6

Moved (insertion) [1]

Moved up [1]: Participating Organizations will display information about their participation in the HIE Entity in patient-accessible locations. Information display can include displaying HIE Entity-provided posters and fliers in patient waiting areas, including information about participation in the HIE Entity on the Participating Organization’s website, etc.

Deleted: Should the Participating Organizations be required to display information about their participation in the HIE in a patient-accessible location (waiting area, website, etc.)?¶
 Proposed language:



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Entity will limit the sharing of information with the HIE Entity (i.e., can the patient restrict the sharing of their information with the HIE Entity by the Participating Organization).

2.1.5.2. Responsibilities of Patients and Their Representatives – Questions for discussion:

- Are there any specific expectations for patients and their representatives (e.g., acknowledging receipt of notice of privacy practices related to HIE)?

2.2. Additional Policies Needed to Support the Patient and Provider Identity and Care Map Use Case

2.2.1. Questions related to discussing the need for additional policy recommendations:

- Are the current proposed policy recommendations regarding notification disclosure sufficient to cover the Patient and Provider Identity and Care Map use case?
 - Is there a need for the CPDG to develop a patient opt-out policy to support this use case? If so, should it apply to all Participating Organizations or only to certain ones?
 - Is there a need for the CPDG to develop a patient opt-in policy to support this use case? If so, should it apply to all Participating Organizations or only to certain ones?
- What mechanisms for opt-out should be made available to patients? Should it be sufficiently granular to apply to a specific Participating Organization? If so, should it also include a global opt-out for all HIE activities to which an opt-out policy could apply?
- Should the Participating Organizations be involved in the opt-out process beyond informing the patient of their options through the Disclosure Notification Policy process?
- What are the responsibilities of the HIE Entity?
- What are the responsibilities of the Participating Organization?
- What are the responsibilities of the Patient?

3. Recommendations for the Structure and Process for Ongoing Consent Policy Development

3.1. Purpose

The Consent Policy Design Group provided recommendations for only the initial use case presented for development: Patient and Provider Identity and Care Map. The CPDG recommends that the ongoing work of consent policy development be maintained through a standing Consent Policy Committee, the purpose of which is to provide recommendations through the HIT Advisory Council to the HIE Entity on policies related to consent, privacy and patient data confidentiality in support of its mission to facilitate health information exchange among Connecticut providers.



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The Consent Policy Committee serves as an advisor to the HIE Entity as it considers how best to facilitate exchange in compliance with federal and state regulations while maintaining transparency regarding operations of the HIE Entity with patients and other stakeholders. The Consent Policy Committee may be called upon for reviewing and advising on other consent-related matters, such as reviewing technical methods for managing consent.

3.2. Structure Recommendations

The Consent Policy Committee should be established as a standing committee of the HIT Advisory Council and meet on an ad hoc basis to develop recommendations for consent policies for all new use cases and refinements to existing policies as the HIE Entity and stakeholders in exchange gain experience in the implementation of statewide exchange in the state.

3.3. Logistics and Process

In collaboration with the leadership of the HIE Entity, the Connecticut Office of Health Strategy, and the HIT Advisory Council, the Consent Policy Committee should develop a framework analogous to and aligned with the Use Case Factory methodology to review and recommend consent policies that should be applied to each new use case. Previously used policy blocks should be reused as often as is feasible to reduce compliance burden for providers and implementers.

3.4. Policy Structure

Each policy should be developed with the following structure:

- Policy Name
- Purpose
- Application
- Responsibilities of the HIE Entity
- Responsibilities of the Participating Organization
- Responsibilities of the Patient

The HIE Entity should develop a matrix to indicate which consent policy blocks apply to which use cases. An example format is shown below:

<i>Use Case</i>	<i>Use Authority</i>	<i>Rationale</i>	<i>Applicable Consent Policies</i>	<i>Status</i>
Patient and Provider Identity Care Map	HIPAA (TPO)	Essential infrastructure for all exchange functions	Disclosure Notification	Recommended